DECLARATION OF CONFORMITY

The declaration of conformity is issued under the sole responsibility of the manufacturer:

OPTOR S.A.U. Quintana i Millars 2, Nave-G 08940 Cornellà de Llobregat, Barcelona, España

Regulation (EU) 2017/745 of the European Parliament and of the Council, of April 5 2017 on medical devices.

Regulation (EU) 2016/425 of the European Parliament and of the Council, of March 9 2016 on personal protective equipment.

The undersigned declares, under his/her sole responsibility, that the product:

PRODUCT	EYEGLASS FRAMES/EYE PROTECTOR
INTENDED USE	Support and containment of ophthalmic lenses for correction of refractive errors and eye protection
SNR	ES-MF-000030664
BASIC UDI-DI	8445266PEGASO0FBD
CODE EMDN	Q02100202
CODE UMDNS	11-667 Gafas/Eyeglasses
MODEL	ORGANIK HERMETIC
REFERENCE	158

VARIANTS	**NAME**	**DESCRIPTION**	**EAN**
Ref. 158.04	ORGANIK	Clear lens with UV filter	8436010322962
Ref. 158.05	ORGANIK HERMETIC	Clear lens with UV filter. Inner gasket and removable elastic headband	8436010322986
Ref. 158.09	ORGANIK HERMETIC	Clear lens with UV filter. Inner gasket and fixed elastic headband	8436010322962
Ref. 158.01	ORGANIK	Rx-able with lenses of different materials and filters	8445266003303
Ref. 158.03	ORGANIK HERMETIC	Rx-able with lenses of different materials and filters. Inner gasket and removable elastic headband	8445266003310
Ref. 158.08	ORGANIK HERMETIC	Rx-able with lenses of different materials and filters. Inner gasket and fixed elastic headband	8445266002900

COMPLIES WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS OF THE REGULATION:

Regulation (EU) 2017/745 Medical Devices Regulation
Classification (Rule): CLASS I (Rule 1)

Standards used for the showing compliance with the essential requirements in the specified regulations: **EN ISO 12870:2018, EN ISO 21987:2018, EN ISO 14889:2013/A1:2017, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2021**

Regulation (EU) 2016/425 Personal Protective Equipment
Classification: CATEGORY II

Standards used for the showing compliance with the essential requirements in the specified regulations: **EN 166:2001, EN 170:2002, EN 172:1994/A1:2000/A2:2001**

For the PPE covered by this declaration, the Notified Body has carried out the EU type examination (module B) and issued the EU type certificate no.

EU Type Certificate	Issued by	Notified Body	Certificate date	Valid until
19/2134/05/0161/B	AITEX Asociación de Investigación de la Industria Textil Carretera Banyeres 10, 03802 Alcoy (Alicante)	0161	25/09/2025	25/09/2030

Barcelona, 25/09/2025

OPTOR, S. A.U.
C/. Quintana i Millars, 2, nave G
Tel. 93 204 81 10
08940 CORNELLÀ DE LLOBREGAT
C.I.F.: A-08634917

Iván Gorina Torrents, CEO OPTOR S.A.U

Declaration of Conformity n.º: 158EPIPS.V5.25092025